

REMARKS

The Office Action mailed September 10, 2003, and the prior art relied upon therein have been carefully studied. The claims in the application are now claims 1-37, 45 and 46, such claims defining patentable subject matter warranting their allowance. Accordingly, applicant respectfully requests favorable consideration and early formal allowance.

The Office Action Summary is somewhat confusing as it indicates that claims 1-46 were pending at the time of the Office Action, which is not correct, claims 38-43 having been previously deleted. It is also somewhat confusing to applicants in indicating that claims 1, 5, 11, 12, 14-22 and 45 are both objected to and rejected. It indicates that claim 9 is objected to, but not rejected. It does not mention claims 3, 4, 6-8, 10, 28-30 and 33-35 as being either rejected, allowable or objected to..

Applicant notes that the restriction requirement has been withdraw. As noted above, claims 1-37, 45 and 46 are pending. Claims 3, 4, 6-10, 28-30 and 33-35 have not been rejected on any basis, and accordingly applicant understands that these claims are deemed by the PTO to be directed to allowable subject matter, and in particular to meet the

requirements of 35 U.S.C. 112 and to define novel and unobvious subject matter under §§ 102 and 103.

Claims 13, 26, 27, 36 and 46 have been rejected under the first paragraph of §112 as lacking enablement for all malignant diseases and disorders. This rejection is respectfully traversed.

Nevertheless, amendments are made above to specify breast cancer, blood cancer and prostate cancer, the latter being encompassed by the breadth of applicant's disclosure, and being at least disclosed implicitly, e.g. the person skilled in the art will understand the nature of the common theme of breast cancer and prostate cancer.

That one skilled in the art would be enabled to practice the present invention with respect to prostate cancer is proven in the attached declaration of Prof. Shinitzky, which displays a positive therapeutic affect of 1,3-cycloglycerophosphate on human prostate cancer. Sections 5-7 of such declaration explain the nature of the common theme of breast cancer and prostate cancer and the approach of the present application to their treatment, the proliferation of the cells in order to obtain mature cells which could later be treated by appropriate antagonists.

For the record, the amendments made in response to this rejection are made without prejudice to applicants' rights to pursue in a continuing application broader claims directed to other malignant diseases and disorders which can be treated by a phosphorylation of intracellular proteins without any penalty whatsoever, applicant relying on his rights including those provided by §§119 and 120.

Applicant respectfully requests withdrawal of the rejection.

Claims 17, 25, 31, 32, 36 and 37 have also been rejected under the first paragraph of § 112 as not providing an enabling disclosure for certain terms which appear in these claims. This rejection is respectfully traversed.

Nevertheless, amendments have been made in these claims, again without prejudice in order to resolve this matter at this time, the applicant again reserving his rights to pursue broader claims in a continuing application without any penalty whatsoever, applicant again relying on his rights including those provided by §§ 119 and 120.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1, 2, 5, 11-23, 44 and 45 have been rejected under § 102 as anticipated by each of four different

publications individually discussed below. These rejections are respectfully traversed.

The article by Ayres and Rydon ("The Organic Chemistry of Phosphorous, Part V - the ester interchange reaction between Triphenyl phosphate and glycols") mentions 5- to 8-membered cyclic phosphates where Y-CH₂, X=H and R= phenyl. However, the article does not disclose any therapeutic effect that may be obtained using such compounds nor are there disclosed any pharmaceutical compositions comprising such compounds. While this article is partially relevant to claims 22 and 44, disclosing (among other) certain of such compounds, the article does not disclose the pharmaceutical compositions claimed in claims 1, 2, 5, 11-21 and 45 and the compounds of claim 23.

In view of the disclosure of Ayres et al, claim 44 has been deleted and claim 22 has been amended to exclude 2-methoxy-2-oxo-1,3,2-dioxaphospholane. Thus, Ayres et al cannot be said to anticipate amended claim 22, and does not anticipate any of claims 1, 2, 5, 11-21 or 45.

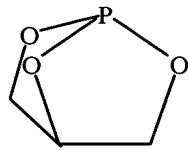
Withdrawal of the rejection under § 102 based on Ayres is respectfully requested.

The article by Shinitzky et al ("formation of 1,3-cyclic glycerophosphate by the action of phospholipase C on phosphatidylglycerol") discloses 6-membered compounds.

However, the article does not disclose any therapeutic effect that may be obtained using such compounds, nor is there disclosed any pharmaceutical compositions comprising such compounds. Thus the article is only partially relevant to claim 44, now deleted, but it is not relevant to claim 22 since these compounds are excluded in paragraph (b) of claim 22 (previously compounds iii, iv and v; now compounds I, ii, and iii). Furthermore, the article does not disclose the pharmaceutical compositions claimed in claims 1, 2, 5, 11-21 and 45.

In view of the deletion of claim 44, and the fact that Shinitzky et al does not anticipate any of the other claims, the rejection should be withdrawn. Such is respectfully requested.

The article by Denney et al deals with 2,6,7-trioxa-1-phosphabicyclo[2.2.1.]heptane having the following chemical structure:



Applicant does not see any resemblance between such a compound and the compounds mentioned in the present

application, let alone the fact that the article does not mention any therapeutic activity or any pharmaceutical compositions comprising such compounds. Denney et al does not anticipate any of applicant's claims

Withdrawal of the rejection is in order and is respectfully requested.

The article by Haimovitz et al in Life Sciences (2001) 69, 2711-2733 was published after the priority date of the application and after the international (PCT) filing date of the present application. Thus, Haimovitz is not prior art.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1, 2, 5, 22, 23, 44 and 45 have been rejected as obvious under § 103 from Watanabe et al USP 6,346,594 (Watanabe). This rejection is respectfully traversed.

Watanabe deals with "ocular material and process for producing the same." The ocular material is a long silicone polymer where, in one of the possibilities, it is a phosphorylethyl ammonium betaine grafted polymer shown on line 50 of column 23. Indeed the 5-membered ring, "2methoxy-2-oxo-1,3,2-dioxaphospholane" mentioned in "Reaction formula (B)" at the top of column 23 is used for synthesizing the

silicone compound in "Reaction formula (C)" in that column at line 50.

This compound is indeed included in the definitions of the compounds of claim 22 (where an appropriate proviso was inserted). However, the compound is mentioned as a **synthetic tool**, as an intermediate in synthesizing the desired polymer. A general broader formula (V) is mentioned in claim 2 covering 4-23-membered cyclic rings, where only the 5-membered ring is exemplified (Example 5, column 50).

Nowhere does Watanabe mention, teach or hint on any other use of the 5-membered compound. Put in other words, nowhere does Watanabe hint or mention that the synthetic tool, namely the 2-methoxy-2-oxo-1,3,2-dioxaphospholane, may have any therapeutic activity or that it may be part of pharmaceutical composition, surely not for the specific therapeutics of the present application.

To summarize, the difference between applicant's claimed invention and the compounds in Watanabe are not only what is acknowledged by the PTO in the second paragraph on page 12 of the Official Action, but also the fact that applicant is claiming a pharmaceutical composition, and not simply a compound. Thus, even if the compounds were identical, there is nothing in Watanabe which would have led the person of ordinary skill in the art to use such a compound

as a pharmaceutical, i.e. to provide such a compound with a pharmaceutically acceptable excipient in an amount sufficient for a pharmaceutical dosage. To put it another way, the person of ordinary skill in the art, reading Watanabe, would never have found it obvious to formulate a pharmaceutical composition with the disclosed compound from the Watanabe disclosure.

Applicant's claims define non-obvious subject matter over Watanabe. Withdrawal of the rejection is in order and is respectfully requested.

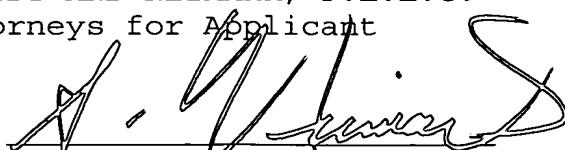
Attached also is a copy if Forrest et al mentioned in applicant's specification.

Applicant respectfully requests favorable reconsideration of the rejections of record, and withdrawal of such rejections, and early formal allowance of the present application.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By



Sheridan Neimark
Registration No. 20,520

SN:ma:jaa

Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\C\cohn\Shinitzky4\PTO\amd 12jan04.doc